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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,125	11/21/2003	Franz Birke	1/1421	2235

28501 7590 11/09/2007

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,125	BIRKE ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 9-18* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 3 AND 9-18 ARE PRESENTED FOR EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on September 17, 2007 after the final rejection set forth in the previous Office action dated May 18, 2007. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's amendment filed on September 17, 2007 has been entered. Accordingly, claims 2 and 5-8 have been canceled; claims 3, 13, 15 and 16 have been amended; and claim 18 has been added.

Restriction/Election

As per the Office action dated August 31, 2006, claims 9-12 remain withdrawn from consideration under 37 C.F.R. § 1.142(b) as being directed to a non-elected invention. Claims 3 and 13-18 are herein acted on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Pursuant to MPEP § 2173.05(b) a claim may be rendered indefinite by reference to an object that is variable. This claim contains dosage amounts expressed as "mg/kg". This unit of measure is a rate of administration dependent upon the weight of the intended host which is variable.

While "mg/kg" is clearly proper for use in expressing the rate of administration in "method of treatment"-type claims, i.e., where a host is a material element of the claimed subject matter, such is not true here because the present claims are directed to compositions of matter which contain neither a host or a step of administration as a material element.

Accordingly, the claim is deemed properly rejected.

Claim 18 Not Further Rejected

As noted *supra*, the subject matter of present claim 18 is considered indefinite by the Examiner. Under MPEP § 2173.06, when the terms of a claim are considered indefinite, at least two approaches to the examination of an indefinite claim *relative to the prior art* are possible and include: (A) where the degree of uncertainty is not great and the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, a rejection over the prior art teaching is a proper where the interpretation is made clear; and (B) where there is a great deal of uncertainty as to the proper interpretation of the limitations of a claim, it would not be proper to reject such a claim on the basis of prior art.

The Examiner deems circumstance "(B)" applies here and thus, claim 18 is not included among the claims rejected *infra* under 35 U.S.C. § 103(a).

Claim Rejection - 35 USC § 103

Claims 3 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderskewitz et al., (U.S. Patent No. 5,731,332, cited by Applicants) in view of Gregory et al., (U.S. Patent No. 6,172,096, cited by Applicants), each of record, for the reasons of record as set forth in the previous Office action dated May 18, 2007 as applied to claims 2, 3, 5-8 and 13-17, which reasons are here incorporated by reference.

Applicants' remarks at pages 7-9 of the amendment referenced at the outset of this Office action have been carefully considered, but fail to persuade the Examiner of error in maintaining this rejection.

Applicants have traversed the present rejection on the basis that the prior art fails to teach or suggest the allegedly synergistic results shown in the present specification and, in light of the Examiner's previous comments as well as the amendments to the claims, that the scope of the claims and of the data are commensurate.

The Examiner continues to acknowledges that the specification at page 16, lines 20-25 establishes a super-additive result which would not have been expected from the teachings of the prior art. The present claims, however, continue to not be commensurate in scope with these results.

Dosage Amounts/Ratios

In particular, claim 3 contains no limitation as to amounts of the active agents present. Also, claim 15 recites a range of ratios of active agents while claim 16 recites a range of

milligram amounts for the combination of actives. Unexpected results, however, have only been shown where the actives were employed in a ratio of LTB4 antagonist:meloxicam of 1:20 and also when administered in a range of rates of administration which varied and were from 0.1 mg/kg formula IA / 2mg/kg meloxicam to 0.8 mg/kg formula IA / 16 mg/kg meloxicam. None of the claims accurately reflect the ingredient ratio and amounts.

Applicants have offered that because unexpected results were shown over a range of dosages, "the data also suggests the synergistic effect would be maintained over a range of weight ratios", (amendment pg. 8). This position, however, is based solely in speculation. Also, it has not been explained how the test data is to be interpreted so that one would necessarily arrive at the particular range of ratios as in claim 15.

Thus, the claims are not seen to be quantitative commensurate in scope with the evidence present in the specification.

Composition of Matter Not Unexpected

The unexpected results relating to the treatment of inflammation demonstrated in the present specification are only realized when one practices a method of treating inflammation which includes a step of administering the active agents to a host. The present claims, however, are directed to compositions of matter and thus are not limited by an intended use or function or a step of administration, (see MPEP § 2111.02(II)). Thus, even if the present claims were limited to the actual dosage amounts which provided the synergistic, anti-inflammatory results, the present claims would remain not commensurate in scope with such results.

Accordingly, for the reasons above, the claims are properly rejected and none are in condition for allowance.

This is a continued examination of Application No. 10/719,125. All claims are drawn to the same invention as previously claimed and could have been finally rejected on the grounds and art of record in the next Office action if they had been presented in response to a first action on the merits. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action following a Request for Continued Examination in this case. See MPEP § 706.07(b). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

November 7, 2007